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REVIEW ARTICLE

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Patient-reported outcome measures of edentulous patients restored with implant-supported removable and fixed prostheses: A systematic review

Coral J Yao[1] | Cong Cao[2,3] | Michael M. Bornstein[4] | Nikos Mattheos[1]

[1]Implant Dentistry, Prosthodontics, Faculty of Dentistry, University of Hong Kong, Hong Kong, China

[2]Center of Stomatology, China Japan Friendship Hospital, Beijing, China

[3]ITI Scholar 2016-2017, Implant Dentistry, Prosthodontics, Faculty of Dentistry, University of Hong Kong, China

[4]Oral and Maxillofacial Radiology, Faculty of Dentistry, University of Hong Kong, Hong Kong, China

Correspondence
Nikos Mattheos, Prosthodontics, Prince Phillip Dental Hospital, Hong Kong, China.
Email: nikos@mattheos.net

Abstract

Objective: The aim of this systematic review was to compare patient-reported outcomes measures (PROMs) of implant-supported fixed complete dentures (IFCDs) and overdentures (IODs).

Material and methods: PubMed, Cochrane Library, EMBASE, Scopus and Web of Science were searched, complemented by manual search. Studies published in English up to November 2016 comparing removable with fixed implant-supported prosthesis on fully edentulous patients were included. The review focused on impact on patients' oral health-related quality of life (OHRQoL), satisfaction or other patient-reported outcomes measures.

Results: Of 1,563 initially screened articles, 13 studies including 8 prospective and 5 retrospective studies fulfilled the inclusion criteria. OHRQoL and patient satisfaction were the most common PROMs. When evaluating the levels of evidence, five of thirteen studies were graded as level III and seven reached level II. The only randomized control trial was rated as Ib. The methods used to evaluate PROMs were heterogeneous among studies, and there was a lack of standardization in the measurements employed. In general, IFCD and IOD showed no significant differences when compared for PROMs, with a slight trend of IFCD being superior to IOD in most included studies. However, conflicting results were observed in many aspects such as chewing function, phonetics-related function, overall satisfaction and aesthetics.

Conclusions: Inconsistent results were observed in PROMs when comparing IFCD and IOD for fully edentulous patients. A guideline for standardizing the assessment of PROMs in clinical research is needed in order to produce more meaningful evidence-based information.

KEYWORDS

dental prosthesis, edentulous, implant-supported, outcome assessment (Health Care), patient satisfaction, patient-reported outcomes measures, personal satisfaction, quality of life

1 | INTRODUCTION

There is currently an emerging consensus on the value of patient-reported outcomes measures (PROMs), as dental therapeutic activities should be guided by patients' needs and desires. In 2012, the VIII European Workshop on Periodontology defined PROMs as essentially "subjective" reports of patients' own perceptions of their oral health status and its impact on their daily life or quality of life (oral health-related quality of life, OHRQoL). Such reported outcomes include satisfaction with oral health status and/or oral health care and other nonclinical assessments (Lang & Zitzmann, 2012; McGrath, Lam, & Lang, 2012). Nevertheless, PROMs implementation in clinical research is still relatively limited. Many clinicians might be not familiar with the psychometric properties of PROMs and their potential to supplement and enrich the outcomes of clinical research. Consequently, a well-designed instrument that could help implement PROMs in clinical research and practice would be extremely important.

As implant dentistry is primarily a rehabilitation discipline, it is becoming evident that assessments of clinical parameters alone cannot provide the complete understanding of the benefits to patients' quality of life and well-being. Furthermore, as different treatment modalities within implant dentistry might incur substantially different levels of invasiveness, costs and time commitment, it becomes imperative to be able to assess the impact that each modality can have on patients' reported well-being, so as to better support clinical decision making.

Implants enhance the support, retention and stability of prosthesis for edentulous patients (Awad & Feine, 1998). A significant body of evidence has demonstrated that implant-supported overdentures (IODs) in mandibular fully edentulous patients can lead to improved satisfaction, improved OHRQoL or other surrogate PROMs compared with traditional complete dentures (CDs) (De Bruyn, Raes, Matthys, & Cosyn, 2015). Consequently, a two-implant-retained overdenture has been regarded as the first choice of treatment for the fully edentulous mandible (Feine et al., 2002). In contrast, studies concerning how implants serve the edentulous maxilla are scarce. This can be attributed partly to the anatomic difference of maxilla and mandible. Even without the help of implants, maxillary prostheses are usually well tolerated by patients (Thomason, Heydecke, Feine, & Ellis, 2007). A systematic review pointed out that a maxillary IOD actually failed to improve function, comfort and stability in patients who did not complain about their CD (Andreiotelli, Att, & Strub, 2009).

Furthermore, the impact on PROMs of a fixed versus a removable implant-supported prosthesis is not conclusively addressed in the literature (Emami, Michaud, Sallaleh, & Feine, 2014). Implant-supported fixed complete dentures (IFCDs) have less volume compared than removable IODs. Elimination of the palatal coverage might help reduce the uncomfortable feeling for some patients and might improve taste in individuals with palatal taste buds (Albuquerque et al., 2000; Misch, 2014). However, the anatomic conditions required for IFCDs imply that patients often need to go through bone augmentations, which are more invasive and traumatic procedures with higher treatment costs and longer duration (Sadowsky, 1997). Patients also appear to do better in performing oral hygiene with an IOD (Heydecke et al., 2003). In terms of aesthetics, IODs could better serve patients in need of more lip support through a denture flange. In general, the absolute advantage of either IFCD or IOD is not evident from patient-reported outcomes, while factors such as patients' preferences and their expectations might play a significant role.

The purpose of this systematic review was to assess the existing evidence from edentulous patients' PROMs of their fixed or removable implant-supported prostheses. Furthermore, this study aimed to identify measurement instruments and best practices towards producing a set of guidelines for the implementation of PROMs in clinical research and patient care involving rehabilitation with dental implants.

2 | METHODS

2.1 | Search strategy

A systematic literature review was performed to identify clinical studies published in English presenting patients reported outcome measures (PROMs) from patients with at least one fully edentulous jaw restored with dental implants. The PICO (Patient or population, Intervention, Control or Comparison, Outcome and study types) search strategy was followed, using MeSH keywords specific to the focus question. The review was registered online with NHS PROSPERO database (https://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42016049600).

Five electronic databases were included in the search: PubMed; Cochrane Library; EMBASE; Scopus and Web of Science. The search was run on 29th November of 2016 and included papers published from 1983 to that date. Literature search updates were performed by setting up automatic searches on each database and requesting new record alerts to be sent by email.

A general search strategy was developed as: (a) *Population:* #1 = (edentulous jaw*) OR edentulous; (b) *Intervention:* #2 = (dental prosthesis implant-supported) OR dental implant?; (c) *Comparison:* #3 = (fixed prosthesis) OR fixed denture*, #4 = (((complete denture*) OR overdenture) OR removable denture*) OR removable prosthesis; (d) *Outcome:* #5 = (((((quality of life) OR patient* centered care) OR patient* centered outcome*) OR patient* satisfaction) OR patient* preference*) OR patient* outcome*; (e) Search combination: #1 AND #2 AND (#3 OR #4) AND #5. The search algorithm was modified according to the specific guidelines of each database (Appendix I).

The initial eligibility assessment was carried out independently by 2 authors (CY and CC) based on the title of the study. As the definition of PROMs was inconsistent among studies, the group agreed to adopt broad inclusion criteria at this stage. After thorough consideration, a list of inclusion and exclusion criteria was developed by the authors (Appendix II). Reasons for exclusion were listed and the Kappa value of the final full-text screening was calculated.

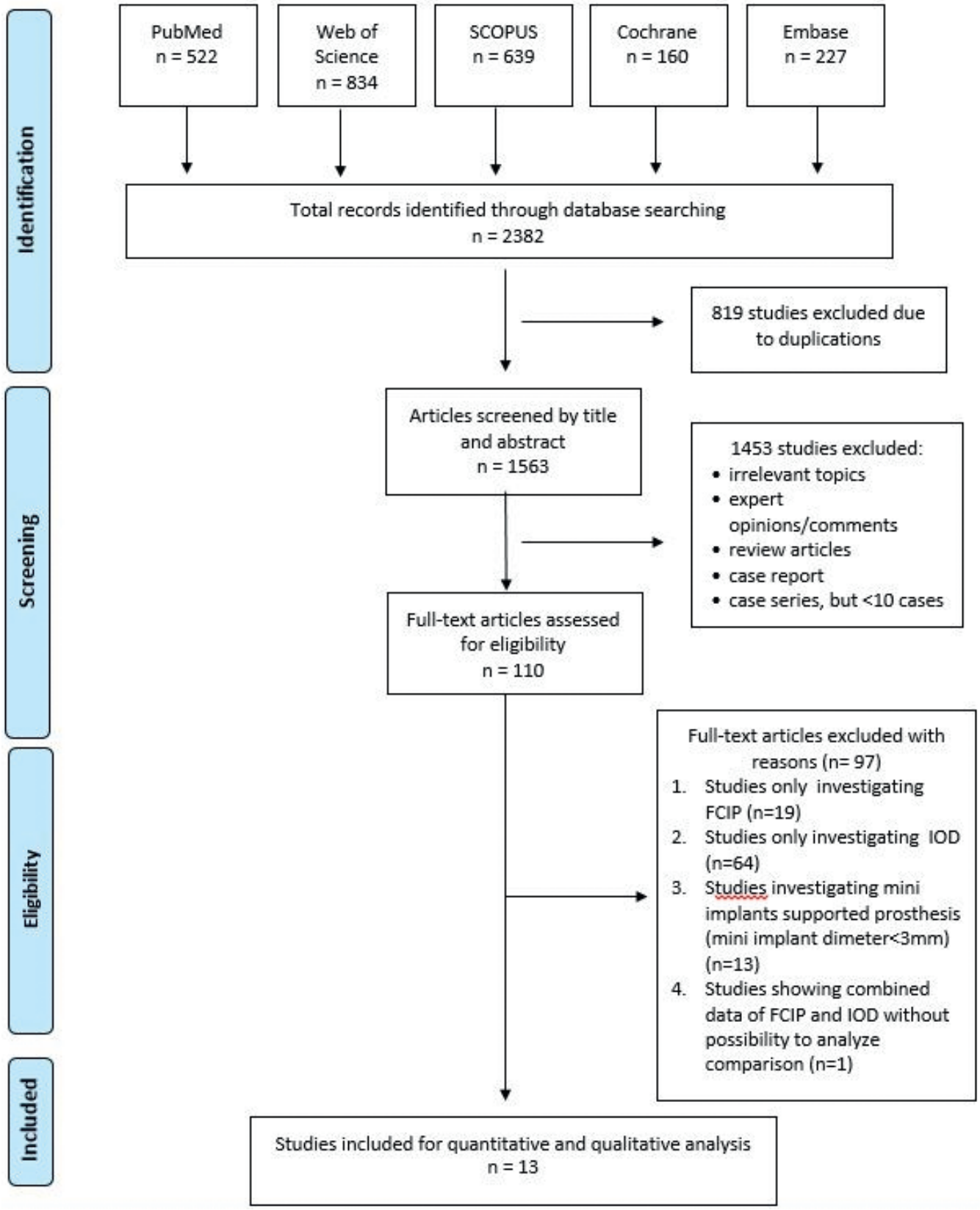

FIGURE 1 Flow chart of publication selection for inclusion

TABLE 1 Number of studies with patient-reported outcome measures (PROMs) in implant dentistry according to year of publication

Time frame	Studies found through searching electronic databases	Final inclusion
1983–1999	170	2
2000–2009	540	4
2010–2016	853	7

2.2 | Data extraction

A data extraction sheet was drafted after reaching consensus within the research group with regards to the important information to be collected. Two authors (CY and CC) independently screened the articles selected and extracted data from included studies. Another two authors (MB and NM) checked the extracted data. Disagreements were resolved by discussion among the four authors.

From each study, data were collected as follows: (a) author information (journal and publish year); (b) study design (retrospective/prospective; nature of investigating PROMs); (c) sample (age; prosthesis distribution; the antagonist type); (d) intervention (implant number; prosthesis type); (e) measurement/timeframe (time point; follow-up time); (f) type of PROMs (OHRQoL; satisfaction, etc.); (g) evaluation method (standard questionnaire; visual analogue scale; Likert-type scale); (h) level of evidence and bias assessment following the guidelines of the US Agency for Health Care Policy and Research (AHCPR, 2012) (Appendix III); (i) results (comparison between IFCD and IOD; comparison of pre- and post-treatment).

3 | RESULTS

After removing duplications, 1,563 articles were identified from 5 different databases (Figure 1). As shown in Table 1, almost 2/3rds of these articles were published during the last 6 years. After excluding the nonrelevant studies at the title stage, the abstracts were screened by two authors, independently (CY and CC). Based on the exclusion criteria presented in the methodology, 1,453 studies were removed. The Kappa value was 0.79. Full texts of the remaining 110 articles were then analysed. Of these, 97 studies were excluded. Reasons for exclusion are presented in Figure 1. Finally, 13 studies met the inclusion criteria and were further analysed, allowing for a comparison of PROMs reported by edentulous patients with fixed (IFCDs) and removable (IODs) implant-supported prostheses.

3.1 | Study characteristics and level of evidence

Details of each study and related PROMs are shown in Table 2. Not all studies reported the treatment protocol followed during the implant surgery and restoration. It was also apparent that the included studies adopted different restoring protocols for implants. Among the 13 publications, 5 studies included patients with fully edentulous maxillae and mandibles; 5 reported prostheses only in the mandible, and 3 investigated prostheses in the maxilla. Not every study stated clearly, if at all, which type of prosthesis was provided in the opposing jaw.

Oral health-related quality of life (OHRQoL) and *Satisfaction* were the most common PROMs in the reviewed papers. All included studies reported either the term "OHRQoL", "Satisfaction" or both. In terms of study design, analysed publications included 8 prospective and 5 retrospective studies. However, in reality many of the studies are cross sectional with regards to the assessment of PROMs, as they only assess PROMs at one time point, even if the design is a prospective cohort with regards to other parameters, for example, incidence of technical complications (Katsoulis, Brunner, & Mericske-Stern, 2011). Determining the actual study design with regards to the investigation of PROMs is therefore not simple and the overall study design might be misleading. Sample sizes ranged from 13 to 150 patients. The assessment time varied from 2 months to 10 years. Among the prospective studies, only 3 (De Kok, Chang, Lu, & Cooper, 2011; Martínez-González, Martín-Ares, Cortés-Bretón Brinkmann, Calvo-Guirado, & Barona-Dorado, 2013; Zitzmann & Marinello, 2000) provided the baseline PROMs, which allowed for prospective assessment pre- and post-treatment. Four publications from the same research group (Feine et al., 1994, 2002), adopted a quasi-randomized cross-over design (De Grandmont et al., 1994; Feine et al., 1994; Heydecke, McFarland, Feine, & Lund, 2004; Heydecke et al., 2003). In addition, one retrospective study by Oh et al. (2016) attempted to investigate PROMs before and after treatment through a one-time face-to-face interview assisted by a questionnaire. The majority of publications did not reach the highest levels of evidence (Table 2). Only one study was graded as level Ib, which also was the only randomized controlled trial (RCT) identified in the present systematic review (De Kok et al., 2011). Five of thirteen studies were graded as level III and seven reached level II.

3.2 | Methodologies of studies

The methods used to evaluate PROMs were heterogeneous among studies. Measurements varied considerably in terms of type of scale and scores calculated. Nine studies utilized a Likert-type scale, seven studies used visual analogue scale (VAS), and two adopted a dichotomous coding system (Table 2). The number of items in the questionnaires ranged from 5 (Feine et al., 1994) to 49 (De Kok et al., 2011). Generally, the Oral Health Impact Profile (OHIP) was widely employed. One study measured the complete OHIP-49 (De Kok et al., 2011), while the short version OHIP-14 was adopted in five studies (Brennan, Houston, O'Sullivan, & O'Connell, 2010; Katsoulis et al. (2011); Martínez-González et al. (2013); Martín-Ares, Barona-dorado, Guisado-moya, Martínez-rodríguez, & Martínez-gonzález, 2016; Oh et al., 2016). However, two of them took items from OHIP-14 in order to create a modified questionnaire. Therefore, wording of the items was inconsistent (Martín-Ares

TABLE 2 Characteristics of included studies

Author	Study design	Sample	Interventions studied	Measurements/ Timeframe	Type of PROMs	PROMs evaluation method	Level of evidence	Results
Oh et al. (2016)	Retrospective Cross-sectional[a] Interview post-treatment	• 86 patients; • Maxilla or Mandible or both • Mean age: o IOD 54.7 o IFCD 54.4 o CD 56.1	29 IFCD; 27 CD; 30 IOD	At least 6 months in function, 69.8% of subjects were examined 1–3 years after receiving new prostheses	• OHRQoL • Satisfaction • Oral health and dental management	• 14 items measuring satisfaction, ad hoc (code = 0–4) • OHIP-14 (code = 0–4)	III	• OHRQoL improved significantly after treatment in both groups • No significant difference of satisfaction or OHRQoL was found between IFCD and IOD
De Souza et al. (2016)	Retrospective	• 75 patients • Mandible	23 IOD: 52 IFCD • Mandible: o 23 IOD 2 implants (bar clip) o 52 IFCD (Brånemark protocol: 4–6 implants) • Maxilla: CD	At least 6 months in function	Satisfaction OHRQoL	9-items survey measuring dichotomous responses (YES/NO) (ad hoc)	III	IFCD was rated higher, but no significant difference of any items was found between IFCD and IOD
Martín-Ares et al. (2016)	Retrospective	• 150 patients • Maxilla and Mandible • Age 60–80	50 IFCD; 50 IOD; 50 CD • Maxilla o IOD 4 implant o IFCD 8 implants; • Mandible: o IOD 4 implants o IFCD 6 implants • Most antagonistic jaw CD	At least 5 years in function	Satisfaction with function and hygiene maintenance	9 items from OHIP-14 and 2 items from the Dental Impact Profile (code = 0–4)	III	• Overall compete satisfaction rate: CD14% significantly lower than IOD 36% and IFCD 46% • No significant difference between IFCD and IOD, apart from IFCD showed significantly lowest satisfaction in self oral hygiene, but better sense of taste
Martínez-González et al. (2013)	Prospective Cohort	• 40 patients • Maxilla and Mandible • Mean age: o IOD 62 o IFCD 61.1	20 IFCD; 20 IOD • Maxilla: o IOD 4 implants o IFCD 8 implants • Mandible: o IOD 2 implants o IFCD 6 implants	• Pretreatment, • Follow-up 1, 3, 5 years	• Impact of prosthetic type on quality of life • Satisfaction	14 items from OHIP-14 and 5 items created by authors (code = 0–4) (ad hoc)	IIb	• For both groups, satisfaction improved significantly over the 1st year, but no significant difference between follow-up 3 or 5 years was found • Generally, no statistically significant differences were found in each item when comparing between IOD and IFCD regardless of study time, but IFCD showed a higher level of overall satisfaction ($p = 0.03$) • Oral hygiene ability was statistically better in IOD after 1 year
De Kok et al. (2011)	Prospective Randomized controlled trail	• 20 patients • Mandible • Mean age: o IOD 62.6 o IFCD 62.4	10 IOD; 10 IFCD (randomized) • Mandible: o IOD 2 implants (ball attachment) o IFCD 3 implants (CAD/CAM) • Early loading protocol • New maxilla CD	• Pretreatment, • 12 months in function	• OHRQoL; • Satisfaction	• 9 items VAS (ad hoc) • OHIP-49 items (code = 0–4)	Ib	• OHRQoL improved after treatment in both groups; • No significant difference of OHRQoL (7 domains) or satisfaction • Patients' reported better capacity of conducting oral hygiene with IOD
Katsoulis et al. (2011)	Prospective[a] Cross sectional[a]	• 41 patients • Maxilla • Mandible partially edentulous • Mean age: 63.3 (52–78)	28 IOD; 13 IFCD • Maxilla: IOD 4,5, or 6 implants: o IOD Gold bar ($n = 16$), o IOD Ti bar ($n = 12$), o IFCD CAD/CAM ($n = 13$) • 8 patients (2 IFCD and 6 IOD treated with flapless procedure	2-years in function	OHRQoL	• OHIP-14 items (code = 0–4)	IIb	• The mean OHIP values were 1.7 (IFCD), 6.7 (gold IOD), and 7.3 (Ti IOD); • Ratings in the IFCD group were significantly better

(Continues)

TABLE 2 (Continued)

Author	Study design	Sample	Interventions studied	Measurements/ Timeframe	Type of PROMs	PROMs evaluation method	Level of evidence	Results
Brennan et al. (2010)	Retrospective	• 62 patients • Maxilla and Mandible • Mean age o IOD 57.5 o IFCD 56	25 IOD; 37 IFCD • Maxilla: o 9 IFCD o 22 IOD • Mandible: o 28 IFCD o 3 IOD Each patient got at least 4 implants	• IOD average follow-up 25.5 months (3–66 months); • IFCD average 24 months (3–80 months)	• OHRQoL; • Satisfaction	• OHIP-14 • 14 items survey (ad hoc) (code = 1–5)	III	• IFCD generally showed better patient satisfaction than IOD, especially in aesthetics; chewing capacity and overall satisfaction • OHRQoL scores for IFCD were marginally better in all 7 domains, but significance was only achieved in psychological disability
Quirynen et al. (2005)	Retrospective	• 37 patients • Mandible • Mean age: o IOD 63.7 o IFCD 54.9	• Mandible: o 25 IOD: 2 implants bar/ magnet/ball attachments o 12 IFCD: No information • Maxilla CD	At least 10-years in function	Satisfaction	• Likert-type scale-5 items (code = 1–9); • YES/NO type-4 items • 14 items VAS (ad hoc)	III	IFCD group presented with significantly higher scores for general satisfaction and chewing comfort
Heydecke et al. (2004)	Prospective[a] Cross-over Cross sectional[a]	• 30 patients, • Maxilla • Age 30–60	Trail 1: mandible IOD • LBO1[b]: maxilla 5 IOD without palate (6 implants) • Maxilla 8 IFCD Trail 2: mandible IFCD • LBO2[b]: maxilla 6 IOD without palate (4 implants) • LBOP[c]: maxilla 7 IOD with palate coverage	2 months after each treatment	Speech	• VAS (ad hoc)	IIa	Statistically significant difference in the ability to speak was only found in Trial 1: subjects with LBO (IOD) perceived their ability to speak was better than the subjects with IFCD.
Heydecke et al. (2003)	Prospective Cross-over	• 13 patients • Maxilla • Mean age 45.1	• Maxilla: o 4–6 implant-supported prostheses o 5 LBO[b]: IOD without palate (bar) o 8 IFCD no information • Mandible: IOD	• Pretreatment • 2 months after each treatment	• Satisfaction • Choice of prosthesis	• VAS • Likert-type scale (ad hoc)	IIa	• IOD significantly higher in general satisfaction (e.g., general satisfaction as compared to the natural teeth;ability to speak and ease of cleaning) • No difference was found for comfort, stability, aesthetics, occlusion or ability to chew • In assessing embarrassment at work and avoiding conversation, IFCD scored inferior to LBO [b] IOD • Among 13 subjects, 4 preferred IFCD compared to 9 IOD
Zitzmann and Marinello (2000)	Prospective	• 20 patients • Maxilla • Age: 35–79	• Maxilla: o 10 IOD (bar) o 10 IFCD no information • Mandible: No information	• Pretreatment; • 6 months post-treatment	• Oral health psychological impact	• VAS (ad hoc)	IIb	• There was no significant difference between IOD and IFCD group • Both groups significantly improved comparing pre- and post-treatment
De Grandmont et al. (1994)	Prospective Cross-over	• 15 patients • Mandible • Mean Age: o IFCD 49.5 o IOD: 58.1	• Mandible o 7 IOD; o 8 IFCD • Maxilla CD	• Pretreatment; • 2 months after each treatment	• General satisfaction • Aesthetics; • Ability to speak • Chewing ability • Fit and retention • Function • Quality of life	• VAS • Likert-type (ad hoc)	IIa	• There was no significant difference between IFCD and IOD in general satisfaction; ability to speak and aesthetics; • Significant differences were found in reported chewing ability for harder foods, for example, carrot, apple and sausage. IFCD was rated higher than IOD

(Continues)

TABLE 2 (Continued)

Author	Study design	Sample	Interventions studied	Measurements/ Timeframe	Type of PROMs	PROMs evaluation method	Level of evidence	Results
Feine et al. (1994)	Prospective Cross-over Cross sectional[a]	• 15 patients • Mandible • Mean Age: ○ IFCD 49.5 ○ IOD 58.1	• Mandible ○ 7 IOD; ○ 8 IFCD • Maxilla CD	2 months after each treatment	• Stability • Ability to chew • Ability to clean • Ability to speak • Aesthetics • Choice of prosthesis	• VAS (ad hoc)	IIa	• Stability and ability to chew were significantly higher with IFCD; • Ability to clean was significantly higher with IOD • There was no significant difference in patients' choice of IFCD or IOD, • For IFCD patients mostly valued stability, ability to chew, and ease of cleaning • For IOD, patients mostly valued ease of cleaning, aesthetics and stability

Note. CD, complete denture; IFCD, implant-supported fixed complete denture; IOD, implant-supported overdenture; OHIP, oral health impact profile; OHRQoL, oral health–related quality of life; VAS, visual analogue scale.

"ad hoc" indicates scale without evidence of validity and reliability for measurement of psychometric properties in terms.

[a]Oh et al. (2016); Feine et al. (1994); Heydecke et al. (2004); Katsoulis et al. (2011): Prospective observation of complications or other parameters, but collection of PROMS only conducted at one time point as a cross sectional study. [b]Long bar overdenture without palatal coverage. [c]Long bar overdenture with palatal coverage

et al., 2016; Martínez-González et al., 2013). Regarding evaluation of patient satisfaction, no standard questionnaire was found in the included studies. There was also a lack of consistency in definition of patient satisfaction.

3.3 | Synthesis of reported outcomes

The most common parameters employed in PROMs measurements were listed in Table 3 in the order of frequency in which they were reported. The most frequently reported outcomes involved chewing function (11 studies), phonetic function (10 studies), overall satisfaction (9 studies), aesthetics (7 studies); comfort (5 studies); retention/stability (5 studies), and capacity to conduct oral hygiene (5 studies).

Generally, apart from one study by Heydecke et al. (2003), the trend of IFCD overriding IOD was found in the majority of included studies but not always reaching statistical significance (De Kok et al., 2011; De Souza et al., 2016; Martín-Ares et al., 2016; Martínez-González et al., 2013; Oh et al., 2016; Quirynen et al., 2005). For *chewing function*, the majority of studies (8/11) revealed no significant differences between IFCD and IOD, apart from Feine et al. (1994), Quirynen et al. (2005) and Brennan et al. (2010). When assessing *phonetics*, only Heydecke et al. (2004) reported that patients with IOD had better experiences with speaking compared with IFCD, while other studies did not find significant differences (9/10). With regard to *overall satisfaction*, four studies claimed that patients rated IFCD significantly higher than IOD (4/9) while another four studies found no differences (4/9). Only Heydecke et al. (2003) reported the reverse, that is, IOD achieved better overall satisfaction than IFCD. In terms of *aesthetics*, Brennan et al. (2010) concluded that IFCDs were rated significantly higher than IODs; however, the residual 5 studies were not statistically different. Five studies reached a similar conclusion in patients' *capacity of maintaining oral hygiene* for their new prostheses: patients considered IOD as easier to clean (De Grandmont et al., 1994; De Kok et al., 2011; Feine et al., 1994; Martín-Ares et al., 2016; Martínez-González et al., 2013). In terms of the *retention or stability of dentures*, only Feine et al. (1994) reported higher scores for the IFCD group (1/5), while the remaining four studies found no significant differences. Two studies evaluated the *sense of taste* as an item of PROMs. Only Martín-Ares et al. (2016) found that IOD was reported by patients as negatively affecting the sense of taste. Meanwhile, Feine et al. (1994) and Heydecke et al. (2003) measured patients' preferences for *choice of the prosthesis* in the mandible and maxilla respectively, but no statistical significance was reached.

When comparing assessment before and after treatment, Zitzmann and Marinello, (2000), Oh et al. (2016) and De Kok et al. (2011) agreed that OHRQoL and patient satisfaction were significantly improved in all domains after completion of the treatment with both IOD and IFCD. This was confirmed in studies by Martínez-González et al. (2013) and Quirynen et al. (2005) with long-term follow-up data. In these studies, patients wearing implant-supported prostheses were interviewed retrospectively at 5 and 10 years. The

TABLE 3 Main PROMs compared between IFCD and IOD

	Oh et al. (2016)	De Souza et al. (2016)	De Kok et al. (2011)	Martínez-González et al. (2013)	Martín-Ares et al. (2016)	Brennan et al. (2010)	Katsoulis et al. (2011)	Quirynen et al. (2005)	Zitzmann and Marinello (2000)	Heydecke et al. (2003, 2004)	De Grandmont et al. (1994)	Feine et al. (1994)
Chewing function	(0)	(0)	(0)	(0)	(0)	IFCD (+)	–	IFCD (+)	(0)	(0)	(0)	IFCD (+)
Phonetic function	–	(0)	(0)	(0)	(0)	(0)	–	(0)	(0)	IOD (+)	(0)	(0)
Overall satisfaction	(0)	(0)	(0)	IFCD (+)	IFCD (+)	IFCD (+)	–	IFCD (+)	–	IOD (+)	(0)	–
Aesthetics	–	–	(0)	(0)	–	IFCD (+)	–	–	(0)	(0)	(0)	(0)
Comfort	–	–	(0)	–	–	(0)	–	(0)	(0)	(0)	–	–
Retention and stability of dentures	–	–	(0)	–	–	–	–	–	(0)	(0)	(0)	IFCD (+)
Capacity to conduct oral hygiene	–	–	IOD (+)	IOD (+)	IOD (+)	–	–	–	–	IOD (+)	–	IOD (+)
OHRQoL	(0)	–	(0)	–	–	IFCD (+) only in Psychologic	IFCD (+)	–	–	–	–	–
Social function	(0)	–	–	–	–	–	–	(0)	–	IOD (+)	(0)	–
Pain	–	(0)	–	(0)	(0)	–	–	–	–	–	–	–
Self-esteem improvement	–	(0)	–	(0)	–	–	–	–	(0)	–	–	–
Understanding of the treatment	–	(0)	–	–	–	(0)	–	–	–	–	–	–
Sense of taste	–	–	–	–	IFCD (+)	–	–	–	(0)	–	–	–
Choice of prosthesis	–	–	–	–	–	–	–	–	–	(0)	–	(0)

Note. IFCD, implant-supported fixed complete denture; IOD, implant-supported overdenture; OHRQoL, oral health-related quality of life
(0) means no significant difference between IFCD and IOD groups; (+) indicates the corresponding group showing significantly better than the other; – means not applicable

authors concluded that the reported improvements in patient satisfaction after completion of treatment could be maintained in the long term, regardless of the mode of rehabilitation, that is, IFCD or IOD.

4 | DISCUSSION

There is an increasing expectation to supplement clinical research outcomes with patients' subjective perspective of their treatment. As in previous systematic reviews in this field (De Bruyn et al., 2015), we found that the majority of eligible studies were published recently. This is not surprising, given the fact that PROMs have received increasing research attention in the recent past. The number of studies using PROMs as primary or secondary outcomes has increased significantly in the past decade, especially in reporting quality of life or patient satisfaction (De Bruyn et al., 2015; Lang & Zitzmann, 2012; McGrath et al., 2012; Strassburger, Heydecke, & Kerschbaum, 2004). Nevertheless, the number of methodologically robust trials comparing patient-reported outcomes of implant-supported fixed and removable prosthesis in fully edentulous patients remain small. Furthermore, any attempt to collectively analyse the existing studies, either statistically or in qualitative terms, has proved to be difficult due to diversity of research designs and definitions of PROMs, heterogeneity of measured outcomes, treatment protocols, and measurement techniques. In addition, differences in the restoring protocols between the same type of prosthesis (e.g., number and placement of implants, locators or bar retention, etc.), could theoretically result in different levels of invasiveness, different needs for maintenance, different frequency of complications and possibly different PROMs; however, there is little evidence in support of such differences at present (Katsoulis et al., 2011).

4.1 | Satisfaction or quality of life?

In the reviewed literature, two items are most commonly assessed as PROMs: impact of prosthesis in the "Quality of Life" and patient "Satisfaction". The current widely adopted instrument for measuring impact in the "Quality of Life" category appears to be the Oral Health Impact Profile (OHIP) and its short versions. The full OHIP questionnaire consists of 49 items that cover seven domains: functional limitation, physical pain, psychologic discomfort, physical disability, psychologic disability, social disability, and handicap (Allen & Locker, 2002). However, some authors have claimed that the OHIP is not sufficient to comprehensively present patients' perceptions of prosthetic rehabilitation (Martín-Ares et al., 2016).

While "Quality of Life" was approached with structured questionnaire items, unfortunately, a definition of "satisfaction" was not described in any of included studies. It appears that "satisfaction" is often perceived as a "common sense" outcome, which will not require any further description or definition. This widely spread perception is reflected in the diversity of measurements of patient satisfaction, and is one of the reasons of the increased heterogeneity of the outcomes. Due to the lack of a uniform or at least widely accepted definition, and a valid and reliable construct, "satisfaction" is assessed in many different formats (Sitzia, 1999). Most studies utilized a vaguely defined broad question such as "overall satisfaction", or specific questions regarding satisfaction with chewing, or speaking. The two approaches may have very different outcomes. It has been suggested that an overall "global" question tends to generate false-positive responses from patients, while specific questions might prompt patients to think deeper and give more detailed responses (Awad & Feine, 1998).

In the absence of a definition or wide understanding of "satisfaction", it is not surprising to realize that this term is often used interchangeably with "Quality of Life" (De Souza et al., 2016; Katsoulis et al., 2011; Martín-Ares et al., 2016; Martínez-González et al., 2013). In particular, some studies utilized OHIP to measure OHRQoL, but then discussed the outcomes in terms of patient satisfaction or generated conclusions about satisfaction. There is, consequently, a need to clarify whether one of these terms is actually redundant, if there is a significant overlap in the outcomes or if both of these terms have validity when assessing PROMs in clinical research. To that end, a definition of the term "patient satisfaction" or similar variations would be an invaluable contribution to this field of research. Furthermore, the factors that influence the expression of satisfaction need to be also identified and described, so as to minimize bias and confounding factors when attempting to measure it.

Allen, McMillan, and Locker (2001) compared the change effect size (pre- and post-treatment) of OHRQoL and satisfaction within IOD patients. They found the changes of OHRQoL (measuring by OHIP) were smaller than denture satisfaction (one general scale), and the correlation coefficients between these two parameters were moderate. This might indicate that the OHIP and denture satisfaction scales are capturing different outcomes. Satisfaction is perceived as simple and comprehensible outcome and thus has often been used as a surrogate outcome of PROMs, leading to instruments that are perceived to be more user-friendly for both patients and clinicians. In contrast, OHRQoL is usually measured with multidimensional variables and the concept is probably too abstract for patients and clinicians unfamiliar with PROMs.

Measurement instruments have been published for both satisfaction and OHRQoL (Allen & Locker, 2002; Michaud, De Grandmont, Feine, & Emami, 2012) and studies have acknowledged these instruments as sensitive enough to capture significant clinical differences between treatment modalities (Allen et al., 2001, 2006; Awad, Lund, Dufresne, & Feine, 2002). However, many researchers have attempted modifications or additions to common instruments. Martínez-González et al. (2013) and Martín-Ares et al. (2016) modified OHIP-14 in their studies for measuring OHRQoL. In Martínez-González et al.'s (2013) study, parameters such as halitosis; difficulty cleaning; self-consciousness when smiling; idea that treatment has been a waste of money; and

treatment has not been worth the trouble were added. Similarly, indicators of satisfaction such as the experience of treatment procedure and the fulfilment of patients' expectations have been proposed (De Souza et al., 2016; Weaver et al., 1997). These variables should not be overlooked, in particular when attempting to measure satisfaction, as there is increasing evidence that other parameters than the actual treatment outcome can significantly influence the individual's expression of satisfaction (Yao, Tang, Gao, McGrath, & Mattheos, 2014). For example, in Allen and McMillan's (2003) study, patients were less happy when they requested dental implant-supported prostheses for one edentulous jaw but given complete dentures (CDs) instead. In comparison, patients who preferred implants and received implant prosthodontic treatment were significantly more satisfied. This was the same for patients who preferred complete dentures without implants and were treated in that manner.

4.2 | The influence of patients' characteristics and background

Patient-reported outcomes measures were affected by multiple variables (Martín-Ares et al., 2016; Weaver et al., 1997). For instance, Awad and Feine (1998) demonstrated that patients' gender contributed significantly to the expression of general satisfaction. Allen and McMillan (2003) acknowledged that patients' preferences played an important role in OHRQoL and satisfaction. Patients' expectations/perception of the treatment might affect how they evaluate the success of treatment, as well (Newsome & Wright, 1999; Yao et al., 2014, 2017) . It is, therefore, evident that when measuring satisfaction, certain aspects of patients' demographic, socioeconomic and behavioural characteristics had a significant influence on the expression of satisfaction with the treatment. Unfortunately, there is presently no clear understanding on which patient characteristics would be essential to be reported together with PROMs, in order to better comprehend the outcomes. Consequently, it is no surprise that in the reviewed literature no specific patient characteristics were consistently identified as significant variables, regarding both IFCD and IOD patients. Information regarding the recruited subjects is scarce in most studies. For example, the history of previous prosthetic experiences by patients and the prosthodontic condition of the antagonistic jaw were scarcely reported. Thomason et al. (2007) proposed that the subjects included in a PROMs study should be from truly representative populations, rather than cohorts of previously dissatisfied patients. Allen et al. (2006) suggested that the use of "intention to treat" may have a placebo effect when evaluating "subjective" feeling. If patients are being proactive for implant-related treatment, they might report greater OHIP change scores than those who refuse implants. Consequently, extrapolation of conclusions should be done with caution when there is limited data in the methodology describing the patient sample and characteristics. At the same time, there is an evident need to identify critical information on patients' backgrounds that could assist in the interpretation of the observed PROMs in clinical research.

4.3 | The influence of the treatment environment and settings

Another important parameter that is often neglected is the environment in which treatment takes place. There is increasing evidence, but also widespread anecdotal perception, that patient populations from different treatment centres might differ significantly in terms of their socioeconomic backgrounds, educational level, perceptions and expectations from treatment (Berendes, Heywood, Oliver, & Garner, 2011; Ståhlnacke, Söderfeldt, Unell, Halling, & Axtelius, 2007; Yao et al., 2017). Whether treatment is delivered in government hospitals, private practice, university clinics, subsidized or fully paid care might produce a significant selection bias, as it can filter the patient sample and skew the outcomes in directions that are not easily understood. The very fact that such patients have volunteered to participate in research and that some of them are consequently offered favourable treatment terms with subsidies or other "perks" might also influence patient traits and characteristics. Having established the link between patients' perceptions and expectations with the subjective expression of "satisfaction" implies that a treatment environment and settings which can influence perceptions will also act as a significant confounding factor regarding "satisfaction" (Clow, Fischer, & O'Bryan, 1995; Yao et al., 2014, 2017). All reviewed studies in this paper were conducted in university-affiliated clinics, apart from one study that recruited patients from both private and public clinics (Oh et al., 2016). Nevertheless, there is scarce information towards understanding influences on patients' motivation for treatment such as special conditions, financial subsidies or any other conditions that would benefit study participants compared to those who paid out of pocket for care in private practice and, thus, act as confounders to the reported outcomes.

4.4 | Comparing different treatment modalities

Regarding the direct comparison of PROMs between IOD and IFCD for full-arch rehabilitations, no strong conclusions can be drawn from existing studies. Both advantages and disadvantages were reported for the two treatment modalities. The fixed prosthesis is perceived as a "part of the body" which might provide patients more security and less of a foreign body feeling than the removable option (Misch, 2014). But the IOD is relatively simple, minimally invasive, easier to clean and more affordable (De Souza et al., 2016; Martín-Ares et al., 2016).

As the direct comparison of PROMs between IFCD and IOD failed to lead to consistent conclusions, it might be even more problematic to analyse studies that assess only one or the other treatment modality, such interpretation will most likely suffer from further confounding factors and diversity of methodologies, populations and outcomes.

4.5 | Limitations

This study did not include research directly comparing IFCD versus CD, or studies measuring IOD versus CD. This might have excluded some information which could serve as indirect comparisons between IFCD and IOD. Furthermore, the potential of this review to reach valid conclusions was limited by the diversity in the quality of included studies and the inconsistency in the definition of PROMs. The quality of studies was assessed according to the design of each study, which might not be fully adequate in evaluating risk of bias or other parameters related to quality of evidence. Quantitative analysis of the data was not possible, while qualitative analysis was that of a narrative type.

5 | CONCLUSIVE REMARKS

Overall, there is a scarcity of well-designed studies comparing PROMs from IFCD and IOD treatment. When examining the data from the literature, it is difficult to conclude whether the lack of significant differences in comparing the treatment modalities is due to the actual treatment, the quality of the methodology, the environment in which the treatment took place or patient characteristics. Apart from a clear set of definitions that is urgently needed, other guidelines for introducing assessment of PROMs in clinical research would be a valuable contribution at present. Such guidelines, possibly in the form a "toolkit" could help clinical researchers to select the right tools, collect essential information related to the treatment itself including patients' backgrounds and the environment the treatment takes place. This would lead to outcomes that would be easier to interpret, extrapolate and compare**.** Such a toolkit would offer a boost to PROMs research, which is in the future should be an inherent part of all clinical research.

6 | SUMMARY OF EVIDENCE

Overall, the OHRQoL and satisfaction of edentulous patients were significantly improved after wearing implant-supported prosthesis compared to their OHRQoL and satisfaction ratings before treatment. These improvements can be found in almost all domains, including comfort, function, aesthetics, speech, self-esteem (De Kok et al., 2011; Martínez-González et al., 2013; Oh et al., 2016; Zitzmann & Marinello, 2000).

When comparing between IOD and IFCD, however, the reported outcomes were inconsistent. The majority of the reviewed studies reported that IFCD performed better in the aspects of overall satisfaction and OHRQoL (Table 3), while some authors found IODs and IFCDs were similar when comparing PROMs (Oh et al., 2016; Zitzmann & Marinello, 2000). On the other hand, Heydecke et al. (2003) showed that IODs provided better outcomes in several domains. This controversy may be due to heterogeneities among study methodologies and populations, as PROMs have been reported to be affected by numerous factors (Bryant, Walton, & MacEntee, 2015; Gallucci, Grütter, Nedir, Bischof, & Belser, 2011). In addition, the diversity of measurement tools—with some instruments not being properly validated—may also contribute to this heterogeneity. Conclusively, on the basis of current evidence, it is not possible to support a solid conclusion on which type of prosthesis would result in better PROMs. One clear conclusion appears to emerge however, as 5 studies reached an agreement on the IOD being easier to maintain oral hygiene. This might be of significance when selecting a treatment for patients with difficulties in conducting oral hygiene such as the elderly, patients with disabilities or Parkinson's disease. Meanwhile, it is also apparent that IFCD needs to have a design that allows access for efficient oral hygiene and that patients, who receive such reconstructions, must be adequately trained for their particular prosthesis.

CONFLICT OF INTEREST

The authors declared no conflict of interest and had nothing to disclose.

ORCID

Coral J Yao http://orcid.org/0000-0001-7543-8988
Cong Cao http://orcid.org/0000-0002-5500-061X
Michael M. Bornstein http://orcid.org/0000-0002-7773-8957
Nikos Mattheos http://orcid.org/0000-0001-7358-7496

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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APPENDIX I Search algorithm in five online databases

PUBMED

Population	**#1 = (edentulous jaw*) OR edentulous**
Intervention or exposure	#2 = (dental prosthesis implant-supported) OR dental implant?
Comparison	#3 = (fixed prosthesis) OR fixed denture* #4 = (((complete denture*) OR overdenture) OR removable denture*) OR removable prosthesis
Outcome	#5 = (((((quality of life) OR patient* centered care) OR patient* centered outcome*) OR patient* satisfaction) OR patient* preference*) OR patient* outcome*
Search combination	#1 AND #2 AND (#3 OR #4) AND #5

SCOPUS

(TITLE-ABS-KEY(patient satisfaction) OR TITLE-ABS-KEY(quality of life) OR TITLE-ABS-KEY(patient reported outcome) OR TITLE-ABS-KEY(patient preferences) OR TITLE-ABS-KEY(patient centered care)) AND TITLE-ABS-KEY(dental implant) AND TITLE-ABS-KEY(edentulous) AND (LIMIT-TO(SUBJAREA,"DENT")) AND (LIMIT-TO(LANGUAGE, "English"))

WEB OF SCIENCE

#4	#3 AND #2 AND #1 Refined by: **WEB OF SCIENCE CATEGORIES:** (DENTISTRY ORAL SURGERY MEDICINE) AND **LANGUAGES:** (ENGLISH)
#3	**TOPIC:** (edentulous) *OR* **TOPIC:** (edentulous arch) *OR* **TOPIC:** (edentulism)
#2	**TOPIC:** (dental implant*) *OR* **TOPIC:** (implant supported denture) *OR* **TOPIC:** (oral implant*) *OR* **TOPIC:** (implant supported prosthesis)
#1	**TOPIC:** (patient centered care) *OR* **TOPIC:** (patient reported outcome*) *OR* **TOPIC:** (patient satisfaction) *OR* **TOPIC:** (quality of life) *OR* **TOPIC:** (patient preference*)

EMBASE

#1	**mouth disease/or denture/or mandible/or edentulousness/or implant/or maxilla/**
#2	dental implant.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
#3	patient care/or "quality of life"/or outcome assessment/
#4	patient satisfaction/or doctor patient relation/or interpersonal communication/or motivation/
#5	#3 or #4
#6	#1 and #2 and #5

COCHRANE

#1	**edentulous: ti, ab, kw (Word variations have been searched)**
#2	dental implant*:ti, ab, kw or oral implant*:ti, ab, kw or implant supported prosthesis: ti, ab, kw (Word variations have been searched)
#3	patient centered: ti, ab, kw or quality of life: ti, ab, kw or "patient reported outcome":ti,ab,kw or "patient reported outcome measure":ti,ab,kw or patient satisfaction (Word variations have been searched)
#4	#1 AND #2 AND #3

APPENDIX II INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria	Studies published in English;
	Studies published from 1983 until November 2016
	Quantitative study with clearly stated study design, for example, randomized controlled trial; cohort studies, cross-over studies.
	Healthy patients with fully at least one edentulous jaw treated with complete implant-supported prosthesis
Exclusion criteria	
1st round screening	Case reports or case series (less than 10 subjects)
	Expert opinions, editor comments or any kinds of articles without quantitative data;
	Reviews
2nd round screening	PROMs not being the primary or secondary study outcomes, for example, questionnaire validation
	Studies recruiting fully and partially edentulous patients without presenting separate data
	Studies involving not typical screw type implant-supported prosthesis, for example, zygomatic implant-supported dentures;
	Studies without follow-up period of at least 2 months
	Studies with insufficient data to clarify the outcomes of interest.
3rd round screening	Mini implants (implant diameter less than 3 mm)
	Study separately investigating IFCD or only IOD without comparing them

APPENDIX III

- Ia = evidence obtained from a meta-analysis of randomized controlled trails
- Ib = evidence obtained from at least one randomized controlled trial
- IIa = evidence obtained from at least one well-designed controlled study without randomization
- IIb = evidence obtained from at least one other type of well-designed quasi-experiment study
- III = evidence obtained from well-designed nonexperimental studies, such as comparative, correlational, or case studies
- IV = evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities